Remarks/Arguments

Claims 7, 10, and 12-35 are pending in the application. Claims 12-35 stand withdrawn from consideration pursuant to a restriction requirement.

Claim 7 is allowable. Claim 10 remains rejected as allegedly anticipated by Saitoh *et al*, WO 94/09808 ("Saitoh"). Reconsideration is respectfully requested in view of the following remarks, and the Declaration of Steven Peter Russell Rose, Ph.D. filed herewith ("Rose Declaration")[1]. Dr. Rose is one of the inventors. He is also a renowned researcher, prolific writer and recipient of numerous scientific awards.

Claim 10 is not anticipated by Saitoh. As indicated previously, the "(-)" entry for RER in the table at page 18 (Peptide M3), and the further disclosure at lines 24 to 26, indicates that RER was devoid of the desired growth promoting activity. On the basis of the perceived inactivity of RER (and also RERMS), and other experimental results, Saitoh concluded that at least five amino acids including RERMS (or five amino acids with like side-chain properties) were essential for biological activity. Biological activity of RER is therefore not taught by Saitoh. Indeed, Saitoh teaches away from an therapeutic utility for RER

Examiner alleges that the lack of activity of the RER peptide in Saitoh's hands is not relevant, because Saitoh allegedly teaches the RER peptide was contained in a pharmaceutical composition. This is incorrect.

The RER peptide was formulated by Saitoh in Dulbecco's Modified Eagle's Medium (DMEM), a liquid growth medium for cell cultures. A typical composition of this medium is listed in paragraph 9 of the Rose Declaration. This typically enriched and buffered tissue culture medium is unsuitable for use as a carrier, excipient or filler for pharmaceutical administration (Rose Decl. ¶10). In particular, the phenol red content of the DMEM composition listed in paragraph 9 of the Rose Declaration would be hazardous or even toxic to humans, if taken either orally or parenterally (Rose Decl. ¶10).

It is respectfully submitted that the DMEM tissue culture medium used by Saitoh to formulate peptide RER for delivery to cell cultures is not a pharmaceutically acceptable carrier,

[1] Also submitted herewith is a separate document is Exhibit SPRR1 referred to in paragraph 9 of the Rose Declaration.

filler or excipient within the meaning of claim 10. DMEM is not pharmaceutically acceptable. The RER/DMEM composition used by Saitoh is not a pharmaceutical composition. Claim 10 is therefore not anticipated by Saitoh.

Conclusion and Request for Rejoinder:

Claims 7 and 10, directed to pharmaceutical compositions, are believed to be in condition for allowance. An early action toward that end is earnestly solicited.

Claims 14, 18, 22, 26, 30, 34, depend from either claim 7 or 10, and recite treatment methods using the claim 7 or claim 10 compositions. Pursuant to MPEP 809.04, claims 14, 18, 22, 26, 30 and 34 should now be rejoined with claims 7 and 10, and allowed..

Respectfully submitted

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